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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Christophe Van Landuyt

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LOUIS WOO

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ALEXANDRIA, VA 22314

EXAMINER

YOUNG, RACHEL T

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,200	Applicant(s) LANDUYT, CHRISTOPHE VAN	
	Examiner RACHEL T. YOUNG	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment

1. This office action is responsive to the amendment filed on 9/28/09. As directed by the amendment: claims 1 and 7-9 have been amended, no claims have been canceled, and no new claims have been added. Thus, claims 1-10 are presently pending in the application.

Claim Objections

2. Examiner thanks the applicant for properly addressing the claim objections from the previous Office Action. However, due to the amendments entered, claims 7-8 are now objected to because of the following informalities: Claims 7-8, line 2 recite "includes **an** heat and moisture exchanger", which is suggested to be changed to -- includes **a** heat and moisture exchanger--.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Persson (2002/0156527) in view of Geertsema (6,439,233).

As to claim 1, Persson discloses a gas-treatment device (Fig. 1 below) for use with a tracheostomy tube (Page 1, ¶ 23, ll. 22), the device including an elongate housing (10, Fig. 3 is wider than it is tall) for connection to the tube (Page 1, ¶ 23, ll. 17-22) to extend generally transversely of the tube (Fig. 3, 10 extends to both sides of the tube), a gas passage in the housing (11, Fig. 5), a gas-treatment unit (20, 21, 22) mounted with the housing (Fig. 2 and 4), the gas-treatment unit is displaceable by rotation about an axis (Page 2, ¶ 24) from a first position (Fig. 5) (Page 2, ¶ 27) in which gas can flow from the tube through the gas-treatment unit via the gas passage, to a second position (Fig. 4) (Page 2, ¶ 26, ll. 1-6) in which the gas passage is substantially blocked preventing flow of gas out of the machine end of the tracheostomy tube.

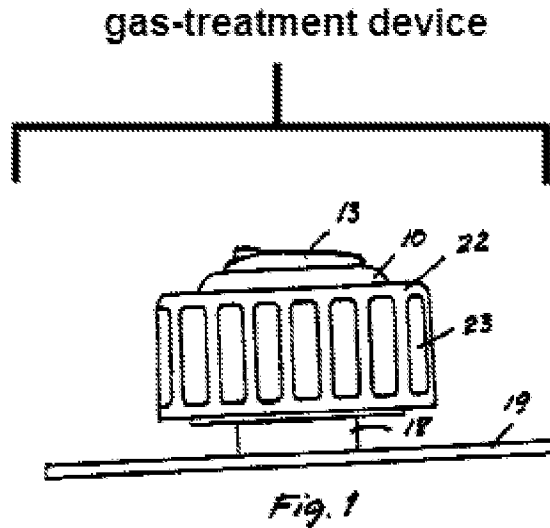
Persson is silent regarding that the rotation of the gas-treatment unit is displaceable about an axis generally transverse to the tube. However, Geertsema teaches a tracheal stoma valve (3, Fig. 1) that is displaceable about an axis generally transverse to the tube. When the user wants the valve to be moved into speaking mode they can inhale more strongly to block exhalation out of valve flap 3 as in fig. 1 and rather the exhaled air will travel up to the vocal cords. If the user wants to return to breathing mode they can exhale more strongly to return the flap to the open position as in fig. 3. Portions of the valve 3 are held in their open and closed positions by magnets as described in Col. 4, ll. 21-46. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Persson's gas-treatment unit with an

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additional valve placed in Persson's cone passageway 18 to be displaceable about an axis generally transverse to the tube, as taught by Geertsema, for the purpose of providing a convenient hands-free way of switching between speaking and breathing modes and also a choice in which speaking mode is more comfortable to them.

In *KSR*, the Supreme Court particularly emphasized "the need for caution in granting a patent based on the combination of elements found in the prior art," *Id.* at ___, 82 USPQ2d at 1395, and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on its precedent that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at ___, 82 USPQ2d at 1395. The Supreme Court further stated that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.



As to claims 2-4, the modified Persson discloses that the gas-treatment unit is displaceable by rotation (Geertsema Col. 4, ll. 21-46), that the gas-treatment unit remains in the first or second position unless manually displaced (Geertsema Col. 4, ll.

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21-46 the user has to use human effort and more strongly inhale or exhale to change the position of the valve), and that the gas-treatment unit includes a projection (Geertsema, 10, Fig. 1) accessible at an end of the housing by which the gas-treatment unit can be displaced (Geertsema Col. 4, ll. 21-46 when the user exhales strongly the air forces projection 10 down to the second position in fig. 3 and when the user inhales strongly the negative pressure moves projection 10 back up as in fig. 1).

As to claim 5, the modified Persson discloses a member (Geertsema valve flap 3, Fig. 3) arranged to displace the gas-treatment unit to a first position when released. The modified Persson is silent regarding that the member is resilient. However, Persson discloses flexible rubber membranes 20 on Page 2, ¶ 24, ll. 2, Fig. 5. It would have been obvious to one of ordinary skill in the art to modify the modified Persson's valve flap with a resilient valve flap, as taught by Persson, for the purpose of providing some give during speaking mode to allow the user to laugh and not change the valve into breathing mode.

As to claim 6, Persson discloses that the gas-treatment unit is cylindrical (Fig. 2).

As to claims 7-8 and 10, Persson discloses that the gas-treatment unit includes a heat and moisture exchanger element (22, Fig. 1, Page 2, ¶ 25, ll. 1), at opposite ends (Fig. 2), and a tracheostomy tube assembly including a tracheostomy tube (18, Fig. 2, Page 2, ¶ 23, ll. 22) and a gas-treatment device (Fig. 1 above) connected at the machine end of the tube (18, Page 2, ¶ 23, ll. 17-22).

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5. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Persson/Geertsema as applied to claim 7 above, and further in view of Turnbull (5,647,344).

As to claim 9, Persson discloses a heat and moisture exchanger element, but is silent that it is made of a treated paper. However, Turnbull teaches a heat and moisture exchanger element that is made of a treated paper (Col. 1, ll. 13-15). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Persson's heat and moisture exchanger element with one of a treated paper, as taught by Turnbull, for the purpose of providing a low resistance to flow, a high efficiency in exchange of heat and moisture, a long life and be easily made at low cost (Col. 1, ll. 24-26).

Response to Arguments

6. Applicant's arguments filed 9/29/09 have been fully considered but they are not persuasive. Applicant recites on page 4, line 10 that claim 1 has been amended to "specify that the housing of the gas-treatment device is elongate and extends generally transversely of the tube". However, Persson discloses an elongate housing 10 in fig. 3, as housing 10 is wider (horizontal span when looking at fig. 3, from 11 to 11) than its height (vertical span of 10, from where 10 is pointing in fig. 3 to 16). The housing 10 also extends transversely on either tube of the tube (when tube is fit into cone 18), as can be seen in fig. 3.

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7. Applicant's additional arguments with respect to claim 1 have been considered but are moot in view of the new grounds of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sorce et al. (3,952,335) to a laryngeal prosthesis with a control valve, Bischoff (6,789,542) to a valved tracheostomy tube, and Verkerke et al. (5,765,560) to a tracheostoma valve. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL T. YOUNG whose telephone number is (571)270-1481. The examiner can normally be reached on mon-thurs 7 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RACHEL T YOUNG/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771